DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 31, 2015

LED Technologies, LLC
% Ms. Susan Anthoney-DeWet
Aegis Regulatory Incorporated
2424 Dempster Drive
Coralville, Iowa 52241

Re: K141181
Trade/Device Name: NUVE FOR WRINKLES
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHS
Dated: March 2, 2015
Received: March 4, 2015

Dear Ms. Anthoney-DeWet:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141181

Device Name
NUVE FOR WRINKLES

Indications for Use *(Describe)*
The Nüve for Wrinkles is an Over-the-Counter (OTC) device intended for the use in treating full-face wrinkles.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K 141181

This 510(k) summary information is being submitted in accordance with the requirements of 21 CFR § 878.4810.
Submission Date: April 1, 2014

1. Submitter Information: AEGIS Regulatory, Inc. – Susan Anthoney-DeWet
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For Specifications Developer: LED Technologies
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2. General Information
2.1 Classification Name: Light Based Over-The-Counter Wrinkle Reduction Device
2.2 Common/Usual Name: Red Light Therapy Device
2.3 Proprietary Names: NÜVE for Wrinkles
2.4 Classification: Class II
2.5 Classification Number: 878.4810
2.6 Product Code: OHS
2.7 Regulation Medical Specialty: General & Plastic Surgery
2.8 Review Panel: Office of Device Evaluation (ODE)
Division of Surgical Devices (DSD)
General Surgery Devices Branch One - Light Based/Laser (GSDB1)

3. Device Description:
The Nüve for Wrinkles is an over-the-counter hand-held light emitting diode (LED) device that emits energy for use in dermatology for the treatment of wrinkles and fine lines. The device uses four types of LEDs : 605nm amber, 630nm red, 660nm red, and 880nm infrared. The treatment time is controlled by the user. There are no user settings or adjustments required.
The Nuve for Wrinkles system components include the handheld unit containing the LED module , power supply, goggles, and travel case.
The unit is applied directly to the skin to ensure consistent administration of light during each treatment. The device does not contain any user serviceable components. The device is sold as Over the Counter (OTC).

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4. Indications / Intended Use:
The Nüve for Wrinkles is an Over-the-Counter (OTC) device intended for the use in treating full-face wrinkles.

Rx or OTC:
The Nüve for Wrinkles is an Over the Counter (OTC) device. The labeling, instructions, and User Operations (21 CFR § 801.60 and 61), are designed for layman understanding and use. The predicate devices are OTC.

5. Predicate Devices:

This device is substantially equivalent to the following predicates, which are currently in safe and effective commerce under product code OHS:
1. K120775 – LightStim for Wrinkles (LED Intellectual)
2. K120560- Trinity Wrinkle Remover (Carol Cole Company)
3. K101382-Dpl NUVE (LED Technologies, LLC)

Device	**NUVE for Wrinkles** **LED Technologies, LLC** **K141181** This Submission	**LightStim for Wrinkles** **LED Intellectual** **K120775** A Predicate Device	**Trinity Wrinkle Remover** **Carol Cole Company** **K120560** A Predicate Device	**Dpl NUVE** **LED Technologies, LLC** **K101382** A Predicate Device
Indications	The dpl- Nüve for Wrinkles is an Over-the-Counter (OTC) device intended for the use in treating full-face wrinkles.	The Lightstim for Wrinkles is an OTC hand-held device intended for the use in the treatment of full-face wrinkles	The Trinity Wrinkle Remover is an OTC hand-held device intended for use in the treatment of full-face wrinkles	The Dpl NUVE is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.
Anatomical Sites	Entire Face	Entire Face	Entire Face	Periorbital
Handheld	Yes	Yes	Yes	Yes
Wavelengths	605,630,660,880nm	605,630,660,855nm	605,628,642,850nm	625, 830nm
Modes	On/Off	On/Off	On/Off	On/Off

Irradiance source	LED	LED	LED	LED
Visible light LEDs	Yes	Yes	Yes	Yes
LED Array/Arrangement	60 LEDs. Over 30cm2	72 LEDs. Over 40cm2	36 LEDs. Over 1.25"D	120 LEDs over 30 cm^2
Energy Level	65 mW total	65 mW total	Unknown	55 mW/cm2
Power Supply	28v DC power supply	9-volt DC power transformer	4 rechargeable batteries	28v DC power supply
Treatment Time	3 minutes daily, 5 days per week for 8 weeks	3 minutes daily, 5 days per week for 8 weeks	3 minutes each area, 21 minutes total minimum 5 days per week for 8 weeks	20 minutes every other day, switching heads
Target Population	Individuals with wrinkles on the face	Individuals with wrinkles on the face	Individuals with wrinkles on the face	Individuals with periorbital lines and wrinkles.
Location for Use	OTC	OTC	OTC	OTC

Summary of the technological characteristics of the device compared to predicate devices:

1. Has the same intended use as the predicate devices (i.e., treatment of full-face wrinkles;
2. Has the similar output (i.e., 65 mW/cm2 **)** as the predicate devices;
3. Utilizes the same number of wavelengths (i.e., 4 wavelengths between **605** nm- **880** nm) as the predicate devices;
4. Utilizes the same treatment duration (i.e., **180** seconds) as the predicate devices;
5. Utilizes the same treatment regimen of five days a week for eight weeks.
The NUVE for Wrinkles device and the above referenced predicate devices are Over the Counter Devices used to treat wrinkles as defined in 21 CFR § 878.4810. These devices utilize red and IR diodes between 605nm to 880 nm to provide narrow bands of light energy to treat wrinkles. The performance achieved by these devices is similar with equal power output. The devices are handheld, and intended to be placed directly on the skin. They are manufactured out of similar materials. Based upon comparison to the predicate devices, the NUVE for Wrinkles device has the same intended uses, with similar technological characteristics as the predicate devices. The system performs as intended and does not raise any new safety or effectiveness issues.

6. Performance Testing and Standards:
Testing of the Nuve for Wrinkles included functional performance testing, software validation testing and user safety testing.
Safety and functionality testing demonstrates that the Nuve for Wrinkles conforms to various international consensus standards:
IEC 60601-1: (2006): Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance.
IEC 60601-1-2: (2007): Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance: Collateral Standard: Electromagnetic Compatibility
IEC 60825-1: (2007)
ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity
Safety Of Laser Products - Part 1: Equipment Classification, And
Requirements
The Nuve for Wrinkles software was tested and validated in accordance with FDA's *"Guidance*
for the content of Premarket Submissions for Software Contained in Medical Devices"
A Usability Study was conducted with 38 participants.
The results of the study found that:
100% of the participants were able to demonstrate the light sensitivity test.
100% of the participants were able to use the device successfully.

The conclusions drawn from nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed devices.

7. Statement of Safety and Effectiveness:
The information in this 510(k) submission was used to support the safety and effectiveness of this device with respect to its cited predicates.

8. Substantial Equivalence Discussion
After analysis of safety, indications, intended uses, dose rates, performance, features, design materials, power output, technological properties, treatment areas, treatment regimes and methods of operation, the manufacturer asserts that no significant differences exist between the applicant device and predicates listed in the predicate chart, and no new issues arise for safety and effectiveness. Therefore, substantial equivalency is hereby requested.